

**EPA REGISTRATION FILE
NUMBER 91090-4**

PROCESSING REQUEST

Reg # 91090-4

Decision # 510372

Description: New Basic CSF dated 9/28/2015

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 9/28/2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tim Ciarlo

Division: RD/IVB1

Phone: 703-347-8082

Date: 7/29/2016



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

91090-4

Date of Issuance:

07/29/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 07/29/2018

Name of Pesticide Product:

Neove Spot On #003 for Dogs

Name and Address of Registrant (include ZIP Code):

Ann M. Tillman
Shanghai Neway Animal Health Co., Ltd.
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 03
Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

07/29/16

2. This registration is time-limited and expires 07/29/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI Orders identified below:

- a. Fipronil GDCI-129121-1305
 GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-pesticide-re-evaluation-division>

6. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 91090-4."

7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 09/28/2015

If you have any questions, please contact Tim Ciarlo by phone at 703-347-8082, or via email at Ciarlo.Timothy@epa.gov.

Neove Spot On #003 for Dogs
MASTER LABEL

Note: [Brackets indicate alternate language] and {braces indicate notes to reviewer}.

Master Label:

1. Carton Label (Front, back, top, bottom, right & left panels)
2. Package Insert
3. Label on Individual Tubes
4. Label on Back of Blister
5. Optional Text for Carton Label/Package Insert

{1. Carton Label: Front Panel}

{Note to Reviewer: The word "Dogs" will be at least 75% in height of the largest letter in the primary brand name.}

Neove Spot On #003 for Dogs

[Alternate Brand Names: FIPRENE PLUS FOR DOGS, FIPMETH PLUS FOR DOGS]

{Drawing of tube}

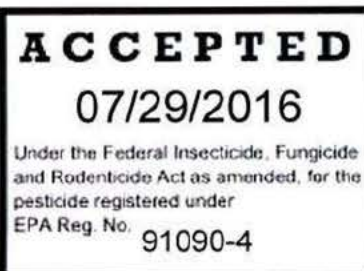
{Picture of appropriate size of dogs}

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes

Kills Ticks, including those that may transmit Lyme disease

Aids in control of sarcoptic mange mite infestations

- [Fast acting]
- [Long lasting]
- [Waterproof]
- [Contains the same active ingredients used in FRONTLINE® Plus for Dogs. This product is not manufactured or distributed by Merial, the maker of FRONTLINE® Plus for Dogs. FRONTLINE® Plus is a registered trademark of Merial.]



For Use ONLY on DOGS and PUPPIES 8 Weeks or Older and 5 to 22 lbs

OR

DOGS 23 to 44 lbs

OR

DOGS 45 to 88 lbs

OR

DOGS 89 to 132 lbs

ACTIVE INGREDIENTS

Fipronil 9.8%

(S)-methoprene 8.8%

OTHER INGREDIENTS 81.4%

TOTAL 100.0%

NET CONTENTS: [X fl. oz (Y mL)]

[[3][4][6][8] - 0.023 fl. oz. (0.67 mL) tubes or 0.045 fl. oz. (1.34 mL) tubes or 0.091 fl. oz. (2.68 mL) tubes or 0.136 fl. oz. (4.02 mL) tubes]

{1. Carton Label: Front Panel}

KEEP OUT OF REACH OF CHILDREN

CAUTION



DO NOT USE ON CATS

{Note to Reviewer: Cat icon will be 1.5 cm x 1.5 cm and will appear on the lower right hand corner of the front panel.}

SEE INSERT AND BACK PANEL FOR FIRST AID AND PRECAUTIONARY STATEMENTS

{1. Carton Label: Back Panel}

Neove Spot On #003 for Dogs

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY AND DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT. DO NOT USE ON CATS, RABBITS OR ANY OTHER ANIMALS.

Neove Spot On #003 for Dogs contains fipronil and (S)-methoprene that effectively kill and control fleas, ticks, chewing lice, mosquitoes and sarcoptic mites for use ONLY on dogs and puppies 8 weeks or older and [weighing 5 to 22 lbs] [weighing 23 to 44 lbs] [weighing 45 to 88 lbs] [weighing 89 to 132 lbs].

Neove Spot On #003 for Dogs remains effective after bathing, water immersion, or exposure to sunlight. Neove Spot On #003 for Dogs is approved for use on breeding, pregnant, and lactating bitches and puppies as young as 8 weeks & weighing at least [5 lbs][23 lbs][45 lbs][89 lbs]. Apply this product ONLY on dogs/puppies 8 weeks of age or older to kill fleas, flea eggs and flea larvae, chewing lice, mosquitoes and all stages of ticks (larva, nymph and adult), including brown dog ticks, American dog ticks, lone star ticks, and deer ticks. This product can also be used to aid in the control of sarcoptic mange mites.

{1. Carton Label: Back Panel}

HOW TO APPLY

- REMOVE and OPEN the child resistant package according to the instructions on package insert.
- To APPLY Neove Spot On #003 for Dogs: Part the dog's hair and place the tip of the tube through the dog's hair to the skin level between the shoulder blades. Squeeze the tube thoroughly to ensure the entire contents are applied in a single spot on the dog's skin. Do not apply the product superficially to the hair coat and avoid contact with the treated area until dry.

FOR EXTERNAL USE ONLY. DO NOT RE-APPLY FOR 30 DAYS.

FREQUENCY OF APPLICATION

FLEAS: When used monthly, this product breaks the flea life cycle and controls flea, flea eggs, and flea larvae on your dog.

TICKS: This product kills all stages of ticks and adult ticks that may transmit Lyme disease for at least one month. For best control of ticks, apply once every month.

CHEWING LICE: This product kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

SARCOPTIC MITES: Apply once a month to aid in the control of sarcoptic mange mite infestation.

MOSQUITOES: Apply once a month to kill mosquitoes within 24 hours for up to 7 days and within 48 hours for up to 28 days.

Side Effects: Monitor your dog after application. Dogs may experience some temporary irritation at the site of application. If signs persist or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment.

{Note to Reviewer: Cat icon will be 1.5 cm x 1.5 cm and will appear on the lower right hand corner of the back panel.}

FOR DOG USE ONLY
DO NOT USE ON CATS

Keep cats away from treated dogs for 24 hours or until product has completely dried.

If applied to or ingested by a cat, contact your veterinarian immediately.



Made in [China]

Manufactured by:

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

Rm. 509, 1438 Shan Xi Bei Road,
Shanghai, 200060

[PRODUCT BAR CODE]

Neove Spot On #003 for Dogs
MASTER LABEL

Note: [Brackets indicate alternate language] and {braces indicate notes to reviewer}.

P. R. China
All rights reserved.
EPA Reg. No. 91090-
EPA Est. No.

{1. Carton Label: Top, Left and Right Panels}

Neove Spot On #003 for Dogs
{Drawing of tube}

For Use ONLY on **DOGS and PUPPIES 8 Weeks or Older and 5 to 22 lbs**

OR

DOGS 23 to 44 lbs

OR

DOGS 45 to 88 lbs

OR

DOGS 89 to 132 lbs

{1. Carton Label: Bottom Panel}

For Dog Use Only
Lot/Batch No.: XXXXXX

Neove Spot On #003 for Dogs
MASTER LABEL

Note: [Brackets indicate alternate language] and {braces indicate notes to reviewer}.

{2. Package Insert}

Neove Spot On #003 for Dogs

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS & PUPPIES OVER 8 WEEKS OF AGE OR OLDER AND WEIGHING [5-22 lbs][23-44 lbs][45-88 lbs][89-132 lbs].

Neove Spot On #003 for Dogs provides a fast-acting, long-lasting and waterproof treatment to:

- Kill Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
- Kill Ticks, including those that may transmit Lyme disease
- Aid in control of sarcoptic mange mite infestations

ACTIVE INGREDIENTS

Fipronil	9.8%
(S)-methoprene	8.8%
OTHER INGREDIENTS	<u>81.4%</u>
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor for treatment advice immediately• Have person sip a glass of water if able to swallow• Do not induce vomiting unless told to do so by the poison control center or doctor• Do not give anything to an unconscious person
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice
If on Skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water and soap for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Hotline Number: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Call 1-XXX-XXX-XXXX for emergency treatment information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS - CAUTION

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

{2. Package Insert}

HAZARDS TO DOMESTIC ANIMALS

For External Use Only. Do NOT use on puppies under 8 weeks of age or weighing less than 5 lbs. Do NOT use on cats, rabbits or any other animals. Sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs of irritation persist, or become more severe, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

Side Effects: Monitor your dog after application. Dogs may experience some temporary irritation at the site of application. If signs persist or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment.

PHYSICAL OR CHEMICAL HAZARDS

Flammable: Keep away from heat or open flame.

Do not mix or allow coming in contact with oxidizing agents. Hazardous chemical reaction may occur.

{2. Package Insert}

DIRECTIONS FOR USE

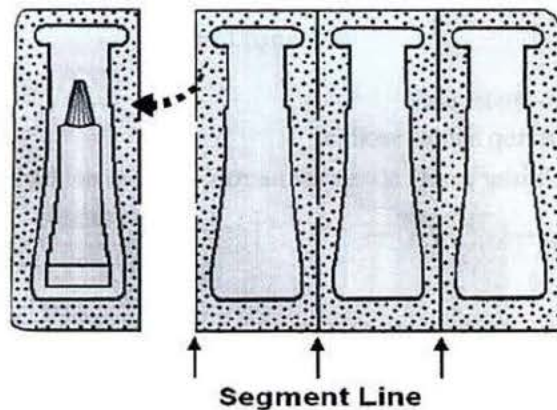
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON CATS, RABBITS OR ANY OTHER ANIMALS.

{For package insert of 0.67 ml (0.023 fl oz) and 1.34 ml (0.045 fl oz) tubes}

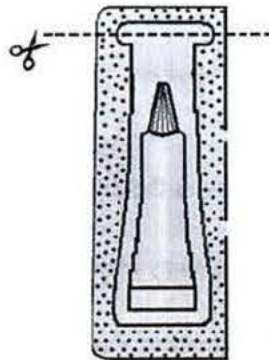


HOW OPEN BLISTER PACK

1. Snap off ONE blister pack along the segment line.



2. Use scissors to cut across the top bubble section (Do not harm the tube inside).



3. Peel off the foil from the cut line and take out the tube.

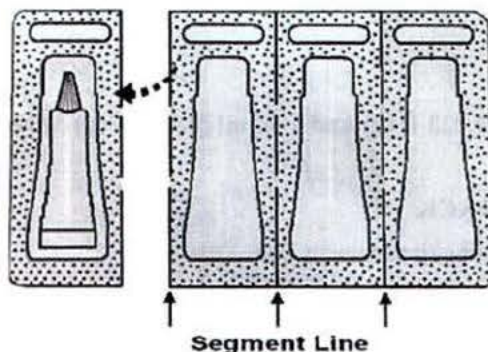
{2. Package Insert}



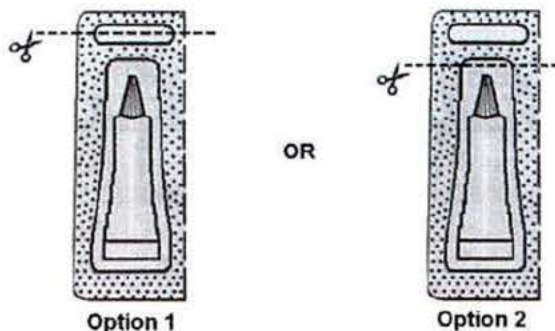
{For package insert of 2.68 ml (0.091 fl oz) and 4.02 ml (0.136 fl oz) tubes}

HOW TO OPEN BLISTER PACK

1. Snap off ONE blister pack along the segment line.



2. Use scissors to cut open the blister pack.
Option 1: Cut across the top bubble section;
Option 2: Cut into the blister cavity across the narrow side (Do not harm the tube inside).



3. Peel off the foil from the cut line and take out the tube.

HOW TO APPLY

Remember, your dog or puppy needs to be dry at the time when this product is applied and must remain dry for 24 hours after application.

1. Hold the tube in an upright position facing away from you and your dog's face and eyes. Screw the cap off the tube.
2. The dog should be standing for easy application. Part the dog's hair and place the tip of the tube through the dog's hair to the skin level between the shoulder blades. Squeeze the tube thoroughly to ensure the entire contents are applied in a single spot on the dog's skin. Do not apply the product superficially to the hair coat and avoid contact with the treated area until dry. Do not use more than one tube per dog per month.

[Visual Depicting Application To Dogs]

3. Make sure the tube is empty after application and discard empty tube as described in the Storage and Disposal section.

{2. Package Insert}

FREQUENCY OF APPLICATION

FLEAS: When used monthly, this product breaks the flea life cycle and controls flea, flea eggs, and flea larvae on your dog.

TICKS: This product kills all stages of ticks and adult ticks that may transmit Lyme disease for at least one month. For best control of ticks, apply once every month.

CHEWING LICE: This product kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

SARCOPTIC MITES: Apply once a month to aid in the control of sarcoptic mange mite infestation.

MOSQUITOES: Apply once a month to kill mosquitoes within 24 hours for up to 7 days and within 48 hours for up to 28 days

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store unused tubes in the original child-resistant package; keep out of reach of children and animals.

Pesticide Disposal: If Partly Filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Handling: Non-refillable container. If Empty: Do not reuse or refill the container. Place in trash or offer for recycling if available.

OPTIONS FOR DIFFERENT DOGS

[Full brand name] comes in four different packages for different sizes of dogs and puppies 8 weeks or older:

- Weighing 5-22 lbs [5-22 lbs] [5 to 22 lbs]
- Weighing 23-44 lbs [23-44 lbs] [23 to 44 lbs]
- Weighing 45-88 lbs [45-88 lbs] [45 to 88 lbs]
- Weighing 89-132 lbs [89-132 lbs] [89 to 132 lbs]

If your dog weighs more than 132 lbs, please consult with your veterinarian.

Do NOT use more than one tube per dog per [month][30 days][4 weeks].

WARRANTY

To the extent consistent with applicable law, Sellers makes no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

{Note to Reviewer: Cat icon will be 1.5 cm x 1.5 cm and will appear on the lower right hand corner of the package insert.}

USE ON DOGS ONLY

DO NOT USE ON CATS OR ANY OTHER ANIMALS



Neove Spot On #003 for Dogs
MASTER LABEL

Note: [Brackets indicate alternate language] and {braces
indicate notes to reviewer}.

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

All rights reserved.

{3. Label on Individual Tubes}

Neove Spot On #003 for Dogs

9.8% Fipronil
8.8% (S)-methoprene

[0.023 fl. oz. (0.67 mL)]

OR

[0.045 fl. oz. (1.34 mL)]

OR

[0.091 fl. oz. (2.68 mL)]

OR

[0.136 fl. oz. (4.02 mL)]

ONLY for [DOGS & PUPPIES 8 Weeks or Older and 5-22 lbs]

OR

[DOGS & PUPPIES 8 Weeks or Older and 23-44 lbs]

OR

[DOGS & PUPPIES 8 Weeks or Older and 45-88 lbs]

OR

[DOGS & PUPPIES 8 Weeks or Older and 89-132 lbs]

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read entire label before each use

[NEWAY]

EPA Reg. No. 091090-

Lot No. 0000000

USE ON DOGS ONLY

DO NOT USE ON CATS OR ANY OTHER ANIMALS



{4. Label on Back of Blisters}

Neove Spot On #003 for Dogs

9.8% Fipronil
8.8% (S)-methoprene

[0.023 fl. oz. (0.67 mL)]

OR

[0.045 fl. oz. (1.34 mL)]

OR

[0.091 fl. oz. (2.68 mL)]

OR

[0.136 fl. oz. (4.02 mL)]

ONLY for [DOGS & PUPPIES 8 Weeks or Older and 5-22 lbs]

OR

[DOGS & PUPPIES 8 Weeks or Older and 23-44 lbs]

OR

[DOGS & PUPPIES 8 Weeks or Older and 45-88 lbs]

OR

[DOGS & PUPPIES 8 Weeks or Older and 89-132 lbs]

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read entire label before each use

[NEWAY]

EPA Reg. No. 091090-

[Lot No. 0000000]

USE ON DOGS ONLY

DO NOT USE ON CATS OR ANY OTHER ANIMALS



{5. Optional Text for Carton Label/Package Insert}

{NON-PESTICIDE RELATED TEXT}

- [Buy “X” get “Y” free]
- [X% more free]
- [[Value Pack]][Great Value]][Bonus Pack]]
- [[Convenient/Easy] to use]
- [[X] month supply]
- [Best results when used monthly (30 days)]
- [Remains effective after [bathing]][swimming]][exposure to sunlight]]
- [Apply directly to your dog’s skin]

{PESTICIDE RELATED TEXT}

- [Provides [Easy], [Fast] and [effective] control of flea, tick, chewing lice, mosquito and sarcoptic mite for dogs and puppies]
- [Effective monthly treatment of [fleas], [ticks], [chewing lice] and [mosquitoes]]
- [Monthly [flea], [tick], [chewing lice] and [mosquitoes] protection]
- [[Prevents] all stages of flea [eggs, larvae, pupae] from developing]
- [Effective [against] all stages of the flea life cycle]
- [[Kills] fleas which may cause [flea allergy dermatitis]][FAD]][flea bite anemia]]
- [Controls flea reinfestations on your dog]
- [[Contains (S)-methoprene, an Insect Growth Regulator, which breaks the flea life cycle]]
- [[Breaks] the flea life cycle]
- [[Dual action: Fipronil & (S)-methoprene IGR]]
- [[A once-a-month application may be needed if dog is at a high risk for flea reinfestation]]
- [[Kills] all stages of ticks [larva, nymph and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), Deer ticks (*Ixodes scapularis*) which may transmit Lyme disease.]
- [[Kills] ticks that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis] and other tick-borne diseases]
- [Kills ticks for up to [4 weeks]][1 month][30 days]]
- [Rapidly [controls] infestations of chewing lice]
- [[Apply monthly to control] chewing lice]
- [[Once a month application] for chewing lice]
- [Kills mosquitoes [within 24 hours for up to 7 days]][and within 48 hours for up to 28 days]]
- [[Controls mites that may cause sarcoptic mange]]



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 91090	2. EPA Product Manager M. Echeverria	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Shanghai Newway Animal Health Co., Ltd./Neove Spot On #003 for Dogs	PM# Invertebrate-Vertebrate Branch 1	
5. Name and Address of Applicant (Include ZIP Code) Shanghai Newway Animal Health Co., Ltd., c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-5 Product Name Frontline Plus for Dogs	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under PRIA Category R315 (48: New end-use non-food animal product with registered sources of active ingredients). The fee is \$8,820 but Shanghai Newway qualifies for a 75% small business waiver. The fee of \$2,205 has been paid.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
			3, 4		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.069, 0.135, 0.273, 0.408 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other on box and on insert in box		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Ann M. Tillman		Title Agent		Telephone No. (Include Area Code) (253)-853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent		DOCUMENTUM	
4. Typed Name Ann M. Tillman		5. Date Oct. 16, 2015			

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

October 16, 2015

MRID 49729700

ELECTRONIC DELIVERY

Marietta Echeverria, Branch Chief
Invertebrate-Vertebrate Branch I
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Shanghai Neway Animal Health Co., Ltd.
Neove Spot On #003 for Dogs (EPA File Symbol 91090-)
Application for New Pesticide Registration
PRIA Category R315

Dear Ms. Echeverria,

On behalf of Shanghai Neway Animal Health Co., Ltd. (SNAH), we are submitting an application for registration of Neove Spot On #003 for Dogs, an end use product containing the active ingredients fipronil and S-methoprene.

In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Proposed Labeling for Neove Spot On #003 for Dogs
4. Formulator's Exemption Statement (EPA Form 8570-27)
5. Certification with Respect to Citation of Data (EPA Form 8570-34)
6. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
7. Public File Copy of the Data Matrix (EPA Form 8570-35)
8. Child Resistant Packaging Certifications for Tube 1 and Tube 2
9. Copy of the May 13, 2015 EPA letter approving the 2015 request for small business waiver
10. Signed Small Business Waiver request for this action
11. Copy of the PRIA payment from pay.gov
12. Letter of Authorization
13. Product Specific Data:

MRID	Volume	Guideline	Report Title
49729701	Volume 1	830.1550, 830.1600, 830.1650, 830.1670, 830.1750	Zhao, J. and Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Formulation Process, Discussion of the Formation of Impurities, and Certified Limits for Neove Spot On #003 for Dogs. <i>Contains Confidential Business Information.</i>

MRID	Volume	Guideline	Report Title
49729702	Volume 2	830.1800	Tao., Z. Enforcement Analytical Methods Validation for Neove Spot On #003 for Dogs.
49729703	Volume 3	Group B 830 Series	Tillman, A. M. Group B Self-Certification of Physical/Chemical Properties for Neove Spot On #003 for Dogs.
49729704	Volume 4	US 16 CFR § 1700	Dixon, L. M. Child-Resistant Protocol Test Child Panel NW-TUBE-1.
49729705	Volume 5	US 16 CFR § 1700	Dixon, L. M. Child-Resistant Protocol Test Senior Panel NW-TUBE-1.
49729706	Volume 6	US 16 CFR § 1700	Dixon, L. M. Child-Resistant Protocol Test Child Panel NW-TUBE-2.
49729707	Volume 7	US 16 CFR § 1700	Dixon, L. M. Child-Resistant Protocol Test Senior Panel NW-TUBE-2.
49729708	Volume 8	870.1300	Tillman, A. M. Neove Spot On #003 for Dogs: Waiver Request for Acute Inhalation Toxicity Data.

Please note that SNAH conducted CRP testing (CRE and SAUE) with two different size tubes (NW-Tube-1 and NW-Tube-2; 4 blisters connected together) each filled with different volumes of placebo water (0.045 and 1.34 fl. oz.). Based on conversations between Maggie Rudick and SNAH, the CRP testing was designed so that the data for these fill volumes, the maximum volume to be added to either tube, could be used to bridge to other fill volumes. The fill volumes for this product include 0.023, 0.045, 0.091 or 0.136 fl. oz. SNAH will package one or two sets of four blisters or one or two sets of three blisters in cartons (total number of units: 3, 4, 6 or 8). SNAH believes that the CRP data can be bridged to all fill volumes, and to packages containing three blisters, and to packages containing 6 or 8 units. The CRP results showed that these packages meet the standards of 40 CFR 157.32(a).

SNAH's Neove Spot On #003 for Dogs qualifies for the Formulator's Exemption for fipronil and S-methoprene generic data requirements. SNAH is using the selective method of data support for certain product specific data. As per EPA's interpretations of 40 CFR Parts 152.90 - 152.96, SNAH submitted notices of intent to apply and offers to pay to the extent required by FIFRA § 3(c)(1)(F).

This application falls under Category R315 (48: New end use non-food animal product). The PRIA fee is \$8,820 but SNAH qualifies for a 75% small business waiver. The fee of \$2,205 has been paid.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

NEWAY

October 13, 2015

Document Processing Desk (COADR)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

To Whom It May Concern:

RE: Letter of Authorization

Please let this letter serve to notify you that Pyxis Regulatory Consulting, Inc. is authorized to represent Shanghai Neway Animal Health Co., Ltd. (EPA Company Number 91090) before the US Environmental Protection Agency in all matters regarding our pesticide producing establishment registration, Neove Spot On #003 for Dogs and Neove Spot On #003 for Cats registrations and applications for registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Zane Liu
President

cc: Janelle Kay; Pyxis Regulatory Consulting, Inc.

Shanghai Neway Animal Health Co., Ltd.

Rm 509, 1438 Shan Xi Bei Rd, Shanghai, China, 200060

Tel: 86 21 5187 7909

Fax: 86 21 6148 4508

Website: www.newaypharm.com.cn

DOCUMENTUM

Child Resistant Packaging Certification – NW-TUBE-2
For Shanghai Neway Animal Health Co., Ltd.'s Neove Spot On #003 for Dogs
(EPA Registration No. 91090-)

Registrant: Shanghai Neway Animal Health Co., Ltd.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32(a).

EPA Registration No. 91090-[pending], Neove Spot On #003 for Dogs is **filled and packaged by Shanghai Neway Animal Health Co., Ltd., Changzhou Branch, 18 Dao Xiang Xi Road, Wujin District, Changzhou, Jiangsu Province, China 213101 (EPA Est. No. 91090-CHN-001).**

The package consists of a placebo filled long tube (7 cm) with a clear plastic front and foil backing that is contained in a blister. The blister has a clear plastic front (PET/PE transparent and colorless) and a foil backing (PET/PA/AL/PE) and silver in color. The sealing method is heat-seal at 125-130°C.

Three or four blisters are connected to each other. The blister is the child-resistant packaging. The pipette has two fill levels, which are 0.091 fl. oz. (2.68 mL) and 0.136 fl. oz. (4.02 mL). Child Resistant Packaging, CRP, testing was conducted on the four blister samples with a placebo filled pipette at fill levels of 0.136 fl. oz. (4.02 mL). The package identification used was NW-TUBE-2. The reference for these CRP reports are:

- 0.136 fl. oz. (4.02 mL) (MRID 49729706 – GLM Child Panel #15244)
- 0.136 fl. oz. (4.02 mL) (MRID 49729707 – GLM Senior Panel #15244).

Shanghai Neway Animal Health Co., Ltd. will package one or two sets of four blisters or one or two sets of three blisters in cartons (total number of units: 3, 4, 6 or 8). Shanghai Neway Animal Health Co., Ltd. manufactures both three and four blisters on the same equipment using the same materials. I realize that additional CRP testing may be required if EPA Registration No. 91090-[pending], Neove Spot On #003 for Dogs is **not filled and packaged by Shanghai Neway Animal Health Co., Ltd. on the same equipment as the samples tested.** Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for EPA Registration No. 91090-[pending], Neove Spot On #003 for Dogs.



Ann M. Tillman
Pyxis Regulatory Consulting, Inc.
Agent for Shanghai Neway Animal Health Co., Ltd.

Oct. 8, 2015
Date


DOCUMENTUM

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date October 16, 2015			EPA Reg. No./File Symbol 91090-		Page 1 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW, Gig Harbor, WA 98332			Product Neove Spot On #003 for Dogs		
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	49729701	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1600	Description of Materials Used to Produce the Product	49729701	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	49729701	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1670	Discussion of Formation of Impurities	49729701	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	49729701	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1800	Enforcement Analytical Method	49729702	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6302	Color	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6303	Physical State	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6304	Odor	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6315	Flammability	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Oct. 16, 2015

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date October 16, 2015

EPA Reg. No./File Symbol 91090-

Page 2 of 4


Applicant's/Registrant's Name & Address

Shanghai Neway Animal Health Co., Ltd.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW,
Gig Harbor, WA 98332

Product

Neove Spot On #003 for Dogs

Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)

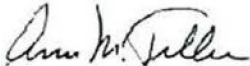
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explodability	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	Waiver ⁴
830.6317	Storage Stability	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6319	Miscibility				Not required ⁵
830.6320	Corrosion Characteristics	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁶
830.7000	pH	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.7050	UV/Visible Absorption				Not Required ⁷
830.7100	Viscosity	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.7200	Melting Point/Melting Range				Not Required ⁷
830.7220	Boiling Point/Boiling Range				Not Required ⁷
830.7300	Density/Relative Density/Bulk Density	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.7370	Dissociation Constants in Water				Not Required ⁷
830.7520	Particle size, fiber length, diameter distribution	49729703	Shanghai Neway Animal Health Co., Ltd.	OWN	Waiver ⁸
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not Required ⁷
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
Signature 			Name and Title Ann M. Tillman, Consultant		Date Oct. 16, 2015

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DATA MATRIX


Date October 16, 2015			EPA Reg. No./File Symbol 91090-		Page 3 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW, Gig Harbor, WA 98332			Product Neove Spot On #003 for Dogs		
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not Required ⁷
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not Required ⁷
870.1100	Acute Oral Toxicity: Rat	44942004		OLD	
870.1200	Acute Dermal Toxicity: Rat	44942005		OLD	
870.1300	Acute Inhalation Toxicity: Rat	49729708	Shanghai Neway Animal Health Co., Ltd.	Waiver	See endnote ⁹
870.2400	Primary Eye Irritation: Rabbit	44942006		OLD	
870.2500	Primary Dermal Irritation	44942007		OLD	
870.2600	Dermal Sensitization	44942008		OLD	
870.7200	Companion Animal Safety	44942104 45143901 45612702 45620507	Merial Limited Merial Limited	OLD OLD PAY PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Oct. 16, 2015

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date October 16, 2015		EPA Reg. No./File Symbol 91090-		Page 4 of 4	
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW, Gig Harbor, WA 98332		Product Neove Spot On #003 for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Product Performance	44942105		OLD	
		44942106		OLD	
		45612701	Merial Limited	PAY	
		45620501	Merial Limited	PAY	
		45620502	Merial Limited	PAY	
		45620503	Merial Limited	PAY	
		45620504	Merial Limited	PAY	
		45620505	Merial Limited	PAY	
		45620506	Merial Limited	PAY	
		45866902	Merial Limited	PAY	
US 16 CFR § 1700	Child Resistant Packaging Study	49729704	Shanghai Neway Animal Health Co., Ltd.	OWN	
		49729705	Shanghai Neway Animal Health Co., Ltd.	OWN	
		49729706	Shanghai Neway Animal Health Co., Ltd.	OWN	
		49729707	Shanghai Neway Animal Health Co., Ltd.	OWN	
Generic Data Requirements					
Shanghai Neway Animal Health Co., Ltd.'s Neove Spot On #003 for Dogs qualifies for the Formulator's Exemption for fipronil and S-methoprene generic data requirements.					
Signature 		Name and Title Ann M. Tillman, Consultant		Date Oct. 16, 2015	

Endnotes for Data Matrix for Neove Spot On #003 for Dogs

-
- ¹ **830.1620** - These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ² **830.1700** – This product does not consist solely of the technical grade active ingredient (TGAI) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ³ **830.6313** – These data are not required for registration of an end-use product.
- ⁴ **830.6316** – Neither the active ingredients, fipronil or S-methoprene, nor any of the inert ingredients in Neove Spot On #003 for Dogs contains the chemical bonds or functional groups associated with chemicals that are explosive. Therefore, a waiver from this data requirement is requested.
- ⁵ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. Neove Spot On #003 for Dogs is not an emulsifiable liquid to be diluted with petroleum solvents and therefore this data requirement is not applicable.
- ⁶ **830.6321** - This product is not proposed for use around electrical equipment. Therefore, these data are not applicable.
- ⁷ **830.7050, 830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** – These data are not required for registration of an end-use product.
- ⁸ **830.7520** – Shanghai Neway Animal Health Ltd. is seeking a waiver for this data requirement for Neove Spot On #003 for Dogs because the product is not a fibrous material or a water-insoluble material.
- ⁹ **870.1300** – A waiver from the requirement of an acute inhalation toxicity study is requested for this formulation. Based on the use pattern (a spot-on treatment for domestic animals), inhalation is not expected to be a significant route of exposure. EPA has previously waived this requirement for similar use products.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Shanghai Neway Animal Health Co., 4110 136th St. Ct. NW; Gig Harbor, WA 98332; 253-853-7369	EPA Registration Number/File Symbol 91090-
Active Ingredient(s) and/or representative test compound(s) Fipronil, S-Methoprene	Date Oct. 16, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood	Product Name Neove Spot On #003 for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., ou=Pyxis, email=Ann@PyxisRC.com, c=US Date: 2015.10.14 12:29:01 -0400	Date Oct. 16, 2015	Typed or Printed Name and Title Ann M. Tillman, Agent
---------------	--	-----------------------	--



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332	EPA File Symbol/Registration Number 91090-
	Product Name Neove Spot On #003 for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 09/28/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil
 (S)-methoprene

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).




(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil (S)-methoprene	 *Product ingredient source information may be entitled to confidential treatment*	
Signature  <small>Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., email=Ann@PyxisRC.com, c=US Date: 2015.10.14 12:24:20 -0400</small>	Name and Title Ann M. Tillman, Agent	Date 10/16/2015

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

DOCUMENTUM



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 22, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-510372
EPA File Symbol or Registration Number: 91090-U
Product Name: Neove Spot On #003 for Dogs
EPA Receipt Date: 21-Oct-2015
EPA Company Number: 91090
Company Name: SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

ANN TILLMAN
PYXIS REGULATORY CONSULTING, INC.
SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.
4110 136TH ST. CT., NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE
TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR
ONLY.;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST
EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Peresa Owens
Front End Processing Staff

Information Technology & Resources Management Division

Ann Tillman

From: notification@pay.gov
Sent: October 15, 2015 6:42 AM
To: Ann Tillman
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25NTJMGG
Agency Tracking ID: 74891105830
Transaction Type: Sale
Transaction Date: 10/15/2015 06:41:51 AM EDT

Account Holder Name: Ann Tillman

Transaction Amount: \$2,205.00
Billing Address: 4110 136th St. NW
Billing Address 2:
City: Gig Harbor
State/Province: WA
Zip/Postal Code: 98332
Country: USA

Registration Number:
Company Name: Shanghai Neway Animal Hea
Company Number: 91090
Action Code: R315

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Receipt for Section 3

S: 975885
Milestone Email: Ann@PyxisRC.com

Regulatory Type: Product Registration - Section 3
Application Type: New Registration
Company: 91090 SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.
Risk Manager: Registration Division, Risk Management Team 3

Resubmission: ☐ Yes ☒ No
Fee For Service: ☒ Yes ☐ No
Billable: ☒ Yes ☐ No

Print Letter
Enter More Information
Tracking

Product #: 91090-U
Product Name: Neove Spot On #003 for Dogs

Override#:
Me Too Section: 65331-5
Me Too Product Name: FRONTLINE PLUS FOR DOGS

Application Date: 16-Oct-2015
Front End Date: 21-Oct-2015
FFS Due Date:
OPP Target Date:

OPP Rec'd Date: 21-Oct-2015
Risk Manager Send Date:
Negotiated Due Date:

Fast Track: ☐
New Ingredient: ☐

Receipt Description:

Portal submission # 8796. Application to registration of new product.

Form A: ☐ Signature Date:
Form B: ☐ Signature Date:

Receipt Content
Study
CSF

View/Edit

New Ingredient Request Date:
New Ingredient Received Date:

DOCUMENTUM

Fee for Service

15
{975885`~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 75

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 3

Receipt No.

S- 975885

EPA File Symbol/Reg. No.

91090-U

Pin-Punch Date:

10/20/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R315

Granted: R315

Amount Due: \$ 8,820

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: _____ Date: _____

Remarks:

Coded in Documentum

DOCUMENTUM

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10-20-15

Experts In-Processing Signature: B.B. Date 10-23-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>91090-U</u>		EPA Receipt Date: <u>10-20-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Documentation: Pass or Fail
 - All Required Forms Complete

Inserts: Pass or Fail
 - Insert not found
 - Submitter contacted 11/3
 - Issue Resolved See Insert Clearance Form
 - Inserts Approved for Non-Food Use

PRN 11-03: Pass or Fail
 - MRID: 497297

Overall Status: Pass or Fail

11/3/15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: June 28, 2016

SUBJECT: Neove Spot On #003 for Dogs. Child Resistant and Senior Adult Use Effectiveness Packaging Evaluation for Child Resistant Packaging (CRP)

Registration No.: 91090-U

PC Code: 129121, 105402

Chemical Names: Fipronil (9.8%) and S-Methoprene (8.8%)

Product Type.: Spot On

ASTM Classification: 8F

CR Packaging Manufacturer: Sichuan HuiLi Industry Co. LTD

Decision No.: 510372

DP Barcode: 430112

Regulatory Action.: Child Resistant and Senior Adult Use Effectiveness Testing

MRID No.: 49729704, 49729705, 49729706, 49729707

40 CFR: 40 CFR Part 157

Fill Volumes: 0.045 fl. oz. (1.34 ml), 4.02 ml

FROM: Lisa Pahel, CR/SAUE Primary Reviewer
Fungicide & Herbicide Branch
Registration Division (RD)

THROUGH: Lindsay Roe, Biologist
Fungicide Branch
Registration Division (RD)

TO: Timothy Ciarlo, Risk Manager
Kable Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (RD)

Introduction

The Registration Division (RD) of the Office of Pesticide Programs (OPP) has requested that the CRP team screen the child resistant effectiveness (CRE) and senior adult use effectiveness (SAUE) study data submitted under the Pesticide Registration Improvement Act (PRIA). The CRP team has reviewed the data submitted in support of the new packaging design to house the subject product.

CRE Study Results Summary for Short tube CR-blister pack, 1.34 ml, NW-Tube-1

<u>40 CFR 157.32 Requirements</u>	<u>Study Results</u>	<u>Acceptability</u> A = acceptable U = unacceptable
Failure level	Access to inside of the package was considered a failure	A
Child received	At the beginning of each test period, the child received 1 card containing four tubes	A
Age and Gender distribution for children	100 children (The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range.) Age 42-44 months 30% Age 45-48 months 40% Age 49-51 months 30%	A
Access rate (Must be greater than 94% in the first 5 min. & 90% after 10 min.)	0 children accessed contents of card before demonstration 3 children accessed contents of card after demonstration 3 children accessed contents of card during the test First five minutes (before demo): 100% Effectiveness Full ten minutes (after demo): 94% Effectiveness	A
Sites	No site was used more than 20% of the time.	A
Testers	No single tester tested more than 30% of the panel.	A
Tamper Resistant Features	Tamper resistant features of the package have been removed prior to testing unless it is part of the CRP.	A
Outer packaging	Outer packaging is not given to the child.	A
Handicaps	No child should have an overt physical or mental handicap.	A
Groups and Familiarity	Children divided into groups of two and testing administered in a familiar environment to the children.	A
Dialogue	Script outlined in 16 CFR 1700.20 followed by tester.	A

Findings	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A
Data collected and verified by:	Great Lakes Marketing Research 3361 Executive Parkway, Suite 200 Toledo, OH 43606	A

SAUE Study Results Summary for Short tube CR-blister pack, 1.34 ml, NW-Tube-1

<u>40 CFR 157.32 Requirements</u>	<u>Study Results</u>	<u>Acceptability</u> A = acceptable U = unacceptable
Failure level	Inability to open the package within the 5-min test period or unable to open and properly re-secure the package during the 1-minute test period was considered a failure	A
Tester received	At the beginning of each test period, the tester received 1 card containing four tubes	A
Age and Gender distribution for adults	50 senior adults Age 50-54 years - 25% (8 males, 17 females) Age 55-59 years - 25% (7 males, 18 females) Age 60-70 years - 50% (15 males, 35 females)	A
Access rate (Must be 90% or greater)	1 adults failed to open the package within the 5-min. test 1 adults failed to open the package within the 1-min test 2 total failures 98% Senior Adult Use Effectiveness	A
Sites	No site was used more than 24% of the time.	A
Testers	No single tester tested more than 35% of the panel.	A
Tamper Resistant Features	Tamper resistant features of the package have been removed prior to testing unless it is part of the CRP.	A

Outer packaging	If the outer package gives the instructions for how to open the CRP, the CRP should be given to the test subject in the packaging. If the outer package does not give instructions relevant to the test, the outer package will not be given to the test subject.	A
Handicaps	No adult should have an overt physical or mental handicap, permanent or temporary illness, or injury which would interfere with his/her effective participation shall be included in the test.	A
Dialogue	Script outlined in 16 CFR 1700.20 followed by tester.	A
Findings	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A
Data collected and verified by:	Great Lakes Marketing Research 3361 Executive Parkway, Suite 200 Toledo, OH 43606	A

Package and Testing Description

Container: NW-TUBE-1

Short tube CR-blister pack, filled 1.34 ml

- Material: PET/PE Plastic & Colorless (transparent)
- Manufacturer: Sichuan HuiLi Industry Co. LTD
- Size/Shape: Blister pack

Sealing Film

- Material: PET/PA/AL/PE & Silver color, liner material= polyamide and aluminum

Package Contents: The package was filled with a placebo and sealed with a heat seal by Shanghai Newway Animal Health Co., LTD

CRE Study Results Summary for Short tube CR-blister pack, 4.02 ml, NW-Tube-2

<u>40 CFR 157.32 Requirements</u>	<u>Study Results</u>	<u>Acceptability</u> A = acceptable U = unacceptable
Failure level	Access to inside of the package was considered a failure	A
Child received	At the beginning of each test period, the child received 1 card containing four tubes	A
Age and Gender distribution for children	50 children (The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range.) Age 42-44 months 30% Age 45-48 months 40% Age 49-51 months 30%	A
Access rate (Must be greater than 94% in the first 5 min. & 90% after 10 min.)	1 children accessed contents of card before demonstration 2 children accessed contents of card after demonstration 3 children accessed contents of card during the test First five minutes (before demo): 98% Effectiveness Full ten minutes (after demo): 96% Effectiveness	A
Sites	No site was used more than 20% of the time.	A
Testers	No single tester tested more than 30% of the panel.	A
Tamper Resistant Features	Tamper resistant features of the package have been removed prior to testing unless it is part of the CRP.	A
Outer packaging	Outer packaging is not given to the child.	A
Handicaps	No child should have an overt physical or mental handicap.	A
Groups and Familiarity	Children divided into groups of two and testing administered in a familiar environment to the children.	A
Dialogue	Script outlined in 16 CFR 1700.20 followed by tester.	A

Findings	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A
Data collected and verified by:	Great Lakes Marketing Research 3361 Executive Parkway, Suite 200 Toledo, OH 43606	A

SAUE Study Results Summary for Short tube CR-blister pack, 4.02 ml NW-Tube-2

<u>40 CFR 157.32 Requirements</u>	<u>Study Results</u>	<u>Acceptability</u> A = acceptable U = unacceptable
Failure level	Inability to open the package within the 5-min test period or unable to open and properly re-secure the package during the 1-minute test period was considered a failure	A
Tester received	At the beginning of each test period, the tester received 1 card containing four tubes	A
Age and Gender distribution for adults	100 senior adults Age 50-54 years - 25% (8 males, 17 females) Age 55-59 years - 25% (7 males, 18 females) Age 60-70 years - 50% (15 males, 35 females)	A
Access rate (Must be 90% or greater)	1 adults failed to open the package within the 5-min. test 2 adults failed to open the package within the 1-min test 3 total failures 97% Senior Adult Use Effectiveness	A
Sites	No site was used more than 24% of the time.	A
Testers	No single tester tested more than 35% of the panel.	A
Tamper Resistant Features	Tamper resistant features of the package have been removed prior to testing unless it is part of the CRP.	A
Outer packaging	If the outer package gives the instructions for how to open the CRP, the CRP should be given to the test subject in the packaging. If the outer package does not give instructions relevant to the test, the outer package will not be given to the test subject.	A

Handicaps	No adult should have an overt physical or mental handicap, permanent or temporary illness, or injury which would interfere with his/her effective participation shall be included in the test.	A
Dialogue	Script outlined in 16 CFR 1700.20 followed by tester.	A
Findings	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A
Data collected and verified by:	Great Lakes Marketing Research 3361 Executive Parkway, Suite 200 Toledo, OH 43606	A

Package and Testing Description

Container: NW-TUBE-2 Short tube CR-blister pack, filled 4.02 ml

- Material: PET/ PE Plastic & Colorless (transparent)
- Manufacturer: Sichuan HuiLi Industry Co. LTD.
- Size/Shape: Blister pack
- Sealing Film
- Material: PET/PA/AL/PE & Silver color, liner material= polyamide and aluminum

Package Contents: The package was filled with a placebo and sealed with a heat seal by Shanghai Newway Animal Health Co., LTD

Conclusion

Based on the submitted data reviewed herein, all CRE and SAUE testing data requirements have been fulfilled for the proposed blister pack filled with 1.34 ml and 4.02ml filled tube.

The data matrix should always include MRIDs 49729704, 49729705, 49729706, 49729707 to fulfill CR data requirement.

Label Revisions

Directions for opening the package must be included on the product label and must exactly match those found on page 20 of MRID 49729705 and page 20 of MRID 49729707. The label language as submitted with this data package is acceptable as it pertains to CRP.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D 430106; **FILE SYMBOL No:** 91090-U; **PRODUCT NAME:** Neove Spot On #003 for Dogs; **DECISION No.:** 510372; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Shanghai Newway Animal Health Co., Ltd

DATE OUT: 05/02/16

SUBJECT: End Use Product Chemistry Review
Product Name: Neove Spot On #003 for Dogs

FROM: Indira Gairola / Product Chemistry Team
CITAB/RD (7505P)

TO: Timothy Ciarlo / Kable Davis, RM 03
IV Branch1 / RD (7505P)

(1) 5/2/16 *818m* 5/10/16

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product "Neove Spot On #003 for Dogs". In support of the registration application, the registrant submitted 830 series product chemistry data with MRID No's. 497297-01 to-03 for group A and submitted self-certification for group B. CITAB has been asked to determine acceptability of the aforementioned data and the proposed Basic CSF(s) dated 09/28/15.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.8%) and (S)-Methoprene (8.80%)
2. Has the registrant claimed substantial similarity to a registered product?
[] Yes; [x] No; [] NA; if yes give the registration number of the cited product.
3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [] No
4. All inert ingredients have been screened by CITAB (Inert Team) and found to be approved for the proposed label uses - [x] Yes; [] No.

DP BARCODE No.: D 430106; **FILE SYMBOL No:** 91090-U; **PRODUCT NAME:** Neove Spot On #003 for Dogs; **DECISION No.:** 510372; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Shanghai Newway Animal Health Co., Ltd

5. Confidential Statement of Formula(s):

☒ Basic - Dated: 09/28/15 Re-submitted-☐ NA

☐ Alternate Re-submitted – Dated: ☐ NA

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☐ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA; acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA

Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☐ No; ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

DP BARCODE No.: D 430106; **FILE SYMBOL No:** 91090-U; **PRODUCT NAME:** Neove Spot On #003 for Dogs; **DECISION No.:** 510372; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Shanghai Newway Animal Health Co., Ltd

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos. Cited
			Yes	No		
830.1550	Product Identity & Composition				A	497297-01
830.1600	Description of materials used to produce the product		x		A	497297-01
830.1650	Description of formulation process		x		A	497297-01
830.1670	Discussion on the formation of impurities		x		A	497297-01
830.1700	Preliminary analysis					
830.1750	Certified limits (158.350)	Standard certified limits	x			CSF dated 09/28/16
		Proposed Limits				
		Justification for wider limits			A	
830.1800	Enforcement analytical method ¹		x		A	Validated method was provided 497297-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

1. If validation of analytical method is not provided, the data requirements should be "N" (Not Acceptable)

DP BARCODE No.: D 430106; **FILE SYMBOL No:** 91090-U; **PRODUCT NAME:** Neove Spot On #003 for Dogs; **DECISION No.:** 510372; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Shanghai Newway Animal Health Co., Ltd

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Clear, slightly viscous liquid	A	497297-03
830.6314	Oxidation/Reduction	Compatible with water, ammonium phosphate, iron powder, turpentine. Incompatible with 5% potassium permanganate;	A	497297-03
830.6315	Flammability	Flash point 40.6°C (Pensky-Martens closed cup Method)	A	497297-03
830.6316	Explodability	This product does not contain explosive material	W	497297-03
830.7000	pH	7.4 (25 °C; 1% aq.; pH of wa aq.; pH of water 5.40)	A	497297-03
830.7100	Viscosity	11.3 cP (mPa s; 20 °C) and 7.6 cP (mPa s; 40°C);		497297-03
830.7300	Density (units)	1.02 g/mL (25°C; pycnometer);	A	497297-03
830.6317	Storage stability Or Accelerated storage stability	Stable at normal and elevated temperatures. Day 0: Fipronil 9.61%, S-methoprene 9.15% Day 14, 54°C:	A	497297-03
830.6320	Corrosion characteristics or Accelerated corrosion characteristics	No leakage or corrosion of the commercial packaging was observed after storage at 14 days at 54°C. No change in color of the formulation was observed after storage at 14 days at 54°C.	A	497297-03

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

DP BARCODE No.: D 430106; FILE SYMBOL No: 91090-U; PRODUCT NAME: Neove Spot On #003 for Dogs; DECISION No.: 510372; PC Code(s): 105402, 129121; ACTION CODE: R315; FOOD Use: No; COMPANY: Shanghai Neway Animal Health Co., Ltd

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted/cited for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. EPA Reg. No. from Product chemistry point of view

- ☐ Similar
- ☐ Not similar,
- ☐ Identical
- ☐ Not identical
- ☒ Not applicable

B. Confidential Statement of formula

C. Confidential Statement of formula

1. Basic CSF (dated 09/28/15)
 - ☒ Acceptable
 - ☐ Not Acceptable
 - ☐ Not Applicable
 - If not acceptable provide the reasons
2. Alternate CSF #1;
 - ☐ Acceptable - #1
 - ☐ Not Acceptable
 - ☒ Not Applicable
 - If not acceptable give reasons

Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline(s): (provide the guideline number & explain)
- ☐ Not required
- ☐ Data cited

D. Group B Product chemistry data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Not required
- ☐ Data cited

Product Label/Draft Label

Recommendations – Yes [x]; No []

If yes, give recommendations below:

1. Since the product was determined to react with oxidizing agents the registrant is recommended to add the following statement under the heading Physical and Chemical hazards on the label.
"Do not mix or allow coming in contact with oxidizing agents Hazardous chemical reaction may occur".

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

June 8, 2016

Subject: NEOVE SPOT ON #003 FOR DOGS
EPA File Symbol: 91090-U
DP Barcode 430109
Action Code: R315
PC Codes: 129121 (Fipronil: 9.8%)
105402 (S-Methoprene: 8.8%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
June 8, 2016

Through: Masih Hashim, Ph.D., Team Leader, Toxicology
CITAB
Registration Division (7505P)

M. Hashim

To: Timothy Ciarlo/Kable Davis
Invertebrate-Vertebrate Branch 1
Registration Division (7505P)

Applicant: SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
129121 Fipronil.....	9.8%
105402 S-Methoprene.....	8.8%
<u>Other Ingredients:</u>	<u>81.4%</u>
TOTAL:	100.0%

BACKGROUND: According to the data matrix (dated October 16, 2015), the registrant is citing the following acute toxicity studies: MRID 44942004 (acute oral LD₅₀); 44942005 (acute dermal LD₅₀); 44942006 (eye irritation); 44942007 (dermal irritation); and 44942008 (dermal sensitization). The registrant has submitted a waiver request (MRID 49729708) for the acute inhalation LC₅₀ requirement. In addition, the registrant is citing the following MRIDs to satisfy the 870.7200 data requirements: 44942104; 45143901; 45612702; and 45620507.

COMMENTS AND RECOMMENDATIONS:

1. According to OPPIN Query the acute toxicity citations MRIDs 449420-04, -05, -06, -07 and -08 were used to support 65331-4.
2. After comparing the CSF (dated Sept. 28, 2015) for 91090-U with that for 65331-4, CITAB concludes that the acute toxicity citations that supported 65331-4 (label declaration: Fipronil 9.8%; S-Methoprene 11.8%) will also support 91090-U (label declaration: Fipronil 9.8%; S-Methoprene 8.8%).
3. The studies in MRIDs 449420-04, -05, -06, -07 and -08 have been previously reviewed (TRB memorandum dated December 12, 1999 for 65331-U). The following is a partial acute toxicity profile for EPA Reg. No. 65331-4 (which would also be appropriate for 91090-U) based on the results of these studies:

Acute oral toxicity	III	Acceptable	MRID 44942004
Acute dermal toxicity	IV	Acceptable	MRID 44942005
Primary eye irritation	IV	Acceptable	MRID 44942006
Primary dermal irritation	IV	Acceptable	MRID 44942007
Dermal sensitization	Negative	Acceptable	MRID 44942008

4. The material received for 91090-U includes a waiver request (MRID 49729708: Tillman, A. (2015) Neove Spot On #003 for Dogs: Waiver Request for Acute Inhalation Toxicity Data. Project Number: SNAH/201503. Unpublished study prepared by Shanghai Neway Animal Health Company Limited. 6p). In this waiver request it is stated that the product is packaged in child-resistant packages containing an applicator which is fully enclosed in a foil backed blister package, with each applicator holding less than 0.2 fluid ounces of formulation (0.023, 0.045, 0.091 or 0.136 fluid ounce), and that EPA has waived this requirement for inhalation toxicity for similar spot-on products.

Based on the registrant's arguments, CITAB concludes that a waiver from the requirement of an inhalation study on this formulation is appropriate, with assignment of this product to toxicity category IV by the inhalation exposure route.

5. Based on the considerations indicated above, the following is the acute toxicity profile for 91090-U:

Acute oral toxicity	III	Cited	MRID 44942004
Acute dermal toxicity	IV	Cited	MRID 44942005
Acute inhalation toxicity	IV	Waived	MRID 49729708
Primary eye irritation	IV	Cited	MRID 44942006
Primary dermal irritation	IV	Cited	MRID 44942007
Dermal sensitization	Negative	Cited	MRID 44942008

6. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 91090-U, as obtained from the Label Review System:

PRODUCT ID #: 091090-00004

PRODUCT NAME: NEOVE SPOT ON #003 FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

7. The precautionary and first aid statements as proposed by the registrant are acceptable.
8. The acute toxicity data requirements for the registration of 91090-U, Neove Spot On #003 for Dogs, have been satisfied.
9. The label specifies the following tube sizes: 0.023 fl. oz. (0.67 mL); 0.045 fl. oz. (1.34 mL); 0.091 fluid oz. (2.68 mL); and 0.136 fl. oz. (4.02 mL), which are associated with the following weight treatment ranges respectively: 5-22 lbs; 23-44 lbs; 45-88 lbs; and 89-132 lbs. The registrant is citing the following MRIDs to satisfy the 870.7200 data requirements (and application rates): 44942104; 45143901; 45612702; and 45620507.
9. The study in MRID 44942104 was reviewed by TRB (May 5, 2000 memorandum for 65331-L). The following is excerpted from the executive summary:

In a companion animal safety study (MRID 44942104) Frontline Plus [Active Ingredients: fipronil:10% w/v; (S)-methoprene:9% w/v] was topically applied (between the base of the skull and the shoulder blades) at dose levels of 0.133 mL/kg, 0.399 mL/kg, and 0.665 mL/kg, to groups of 6 male and 6 female beagle puppies (52-60 days old at initiation) on test Day 1 and again on test Day 29. Controls received no treatment...

No mortality was observed during the study period, and there were no statistically significant, dose-related effects on body weight, clinical biochemistry, or hematology. Some control and test animals in all groups exhibited fecal abnormalities both before and during treatment (e.g., soft, creamy, or mucoid feces and red discharge in feces). Although these signs were considered by the study authors "not to be unusual for puppies", it is possible that they represent an abnormal

condition such as a parasitic infection. According to the report text: "The puppies had received anthelmintic treatments prior to arrival, and received further treatments at the laboratory. However, the schedule of treatments (as well as the material administered) is not reported. One male in the high-dose group exhibited clinical signs (body weight loss early in the study (after fasting for blood collection) and subdued behavior on Day 18), and changes in hematology (stress leukogram, microcytosis and hypochromasia and anisocytosis on Days 15 and/or 29) and clinical chemistry (reduction in albumin and albumin: globulin ratio on Days 15, 29 and 43, and elevated AST and ALT on Day 15). Most of the hematological and clinical chemistry changes observed in this one animal were of a transitory nature; however, the reduction in albumin level persisted throughout the study. Decreased albumin was also observed in one female in the 1X group on Day 15. Because the study was still ongoing when the interim report was released, it is recommended that the final condition of the one high-dose male be ascertained (including any necropsy findings, if a necropsy is conducted). It is also recommended that laboratory reference values for the hematological and clinical chemistry parameters be included in the final report.

Overall, the observed clinical signs and changes in hematological and clinical chemistry parameters did not indicate significant treatment related adverse effects. The package labeling and application instructions indicate that the product is to be used on dogs or puppies 8 weeks or older and should not be used more frequently than once every 30 days. However, the package label does not specify the volume of product to be applied, and because the amounts applied in the study were indicated only as volume of product per kilogram body weight, it was not possible to verify that the amounts used in the study conformed to 1X, 3X and 5X of the amounts on the product label.

It is noted that doses are not stated on the proposed label. TRB concludes that the final dosages, as indicated on the label and as packaged in the applicator tubes, must be consistent with (no more than) the 1X application rate in this study (0.133 mL/kg).

It is also noted that this is an interim report, and there is insufficient information relating to the schedule of individual anthelmintic treatments (as well as the material administered), which should be provided in a final report (or as an amendment to this interim report). For these reasons, the study is currently classified as **Supplementary/Guideline** as a companion animal safety study (OPPTS 870.7200) in dogs (puppies).

10. In response to the TRB review of May 5, 2000 additional information (MRID 45143901) was sent in. This was reviewed by TRB (TXR 5001489, memorandum dated July 11, 2000 for 65331-5) with the following comments:

The material in MRID 45143901 includes vaccination and anthelmintic records for the beagle puppies. According to information in the original report (MRID 44942104) the start of the study was staggered (March 11, 12, 15, 18, 19, or 22 in 1999) for individual dogs; according to the additional information in MRID 45143901 16 puppies (numbers 1-9, 13-16, and 21-23) were treated with Nobivac on March 16 and April 6; 20 (numbers 10-12, 17-20, 24-32, 34-35, 37-38) were treated on March 23 and April 13, and 12 (numbers 33, 36, 39-48) were treated on March 30 and April 20. From information on p. 5 of MRID 45143901: "Each animal received the contents of one vial subcutaneously, on each occasion, according to the manufacturer's instructions."

Also, each animal received two 3-day courses of anthelmintic treatment, Panacur 10% Liquid (a 10% suspension of Fenbendazole) according to the dosage rate set by the manufacturer (0.5 mL/kg bodyweight up to 2 kg, thereafter, 1 mL/2 kg bodyweight or part thereof daily for 3 days).

These vaccinations and anthelmintic dosages appear to have been routinely scheduled procedures in these animals, particularly as all of the puppies were dosed on a regular (albeit somewhat staggered) schedule. This indicates that even though these treatments were given following the initiation of the study, the doses were not given in response to individual occurrences of illness or symptoms. However, it is noted that the Guidelines for OPPTS 870.7200 state that: "Animals should be vaccinated, dewormed, and acclimated for 2 weeks prior to the initiation of the study... Animals should be free of infectious disease which could complicate the interpretation of the study results." In this particular case the sporadic and non-dose related nature of individual clinical observations, taken in conjunction with their relatively minor effects, allow us to overlook this deviation from the usual protocol. It is assumed that the laboratory was under considerable pressure to start the study as soon as possible (the puppies were 52-60 days old at the time of the first treatment) in order to support the use of the product on puppies as young as eight weeks.

At the time the puppy study was originally reviewed, the proposed label dosage rates were not available. The labeling which has recently been received indicates the following:

Dogs & puppies up to 22 lbs	0.67 mL (=0.023 fl. oz.)
Dogs 23-44 lbs	1.34 mL (=0.045 fl. oz.)
Dogs 45-88 lbs	2.68 mL (=0.091 fl. oz.)
Dogs 89-132 lbs	4.02 mL (=0.136 fl. oz.)

Dose levels used in the study in MRID 44942104 were 0.133 mL/kg (1X), 0.399 mL/kg (3X), and 0.665 mL/kg (5X) on test Days 1 and 29. At study initiation, males weighed 1.41 to 3.31 kg and females weighed 1.17 to 2.93 kg.

This reviewer's conclusion is that the 1X dosage rate in the study would support an application rate of 0.67 mL for puppies and dogs weighing ≥ 5 kg ($0.67 \text{ mL/kg} \div 5 = 0.133 \text{ mL/kg}$), **but not for dogs weighing less than 5 kg (=11 lbs)**. If the registrant wishes to propose the use of this product on smaller dogs (those weighing less than 5 kg) then the doses must be adjusted accordingly (for example, we could accept a dosage rate of 0.333 mL for dogs weighing between 5.5 and 11 lbs).

Finally, although the original study (in MRID 44942104) was submitted as an interim report, it covered the period up to Day 43 (or to approximately 2 weeks following the second treatment). The Companion Animal Safety Study Guidelines indicate that if the product label states that a treatment can be repeated (from the proposed label: "Do not reapply FRONTLINE PLUS for 30 days") then the study should also include a repeat treatment, and that observations and measurements of possible treatment-related effects should be reported for 14 days posttreatment (presumably following the second treatment). The period of reporting then for this "interim" study was adequate.

The classification of the Companion Animal Safety Study in MRID 44942104 is upgraded to acceptable. This study supports application of the product to dogs and eight-week old and older puppies at dosage rates not to exceed 0.133 mL/kg.

11. The study in MRID 45612 was reviewed by TRB (memorandum dated October 21, 2002 for 65331-5). The following is excerpted from the executive summary:

In a companion animal animal safety study (MRID 45612702), Frontline Plus (active ingredients: 10% w/v fipronil and 9% w/v (S)-methoprene was topically applied (between the base of the skull and the shoulder blades at one or more spots) to eight week old dogs weighing less than 11 lbs at 1x, 3x and 5x the prepackaged use (0.67 mL/puppy) dosage. Forty-eight beagle dogs (24/sex) were randomly allocated to one control and 3 treatment groups with 6 male and 6 female animals in each group. Controls received no treatment. The formulation was delivered from the...pipettes ...[with] 67 mg of fipronil and 60.3 mg of S-methoprene as 1X dosage. Puppies were exposed to the formulation only on Day 1 when they were at an average age of 57 (50 to 63) days and weighed 1.67 to 3.57 kg. All the test and control animals were isolated for 6 hours after treatment and observed at timely intervals (10 minutes in the 1st hour, then each hour on the hour)... Body weights were measured weekly and blood samples were collected for clinical pathology (hematology and clinical chemistry) on Days 2, 15, and 28...

There were no deaths on the study, no local reaction on the application site and no treatment-related clinical signs in the measured parameters. There were no effects on rectal temperature, body weight, food and/or milk consumption, hematology or clinical chemistry.

Gross necropsy and histopathology revealed no abnormalities, with the possible exception of a few dermal effects at the treated sites (red area on the treated site in a few dogs which in one 3x male was 30 mm in diameter and in another 3x male was 10 mm in diameter...

A single topical application of fipronil (10% w/v) and (S)-methoprene (9% w/v) in a solution at 1x, 3x and 5 times the maximum recommended dose, when given to eight week old dogs (approx. 1.5-3.5 kg) showed no treatment related effects.

*This study (870.7200) is classified **Acceptable** in demonstrating a 5x margin of safety in dogs 8 weeks old or older and weighing less than 11 lbs.*

12. Group mean bodyweights (by sex) are reported on p. 35 of MRID 45612702, and the individual bodyweights are reported on pp. 113-114. The mean weight of the four lowest weight males and four lowest weight females in Group 4 (5X) was 2.265 kg or 4.993 lbs. Based on this, the Agency has accepted this study as supporting a minimum dog/puppy weight of 5 lbs associated with a 0.67 mL (67 mg fipronil and 60.3 mg S-methoprene) dose per puppy.
13. The study in MRID 45620507 was reviewed (TRB memorandum dated October 21, 2002 for 65331-5) with the following comments, as excerpted from the executive summary:

In a special (reproductive) companion animal safety study (MRID 45620507) ML-2,095,988 509T (a topical formulation containing 10% w/v fipronil and 9% w/v (S)-methoprene was administered at 0x (Group 1; sham-treated controls), 1x or 0.133 mL/kg (Group 2) and 3xd or 0.399 mL/kg (Group 3) to groups of 12 adult female beagle dogs prior to and during pregnancy, through parturition and to weaning of the puppies...

The only dose-related effects observed in bitches were pink skin at the application site on days of treatment (recorded 15 times in Group 2, 37 times in Group 3), and pink skin at the application

site on the day following treatment (3 times in Group 3). There were no significant differences between the different groups with respect to mean body weights or for a number of parameters measured at weaning (mean rectal temperatures, mean respiratory rates, or mean heart rates).

There was no indication of an adverse effect on any reproductive parameters (including gestation index, incidence of cesarean section, incidences of stillborn pups, incidences of pups dying between birth and weaning). Although there were somewhat greater percentages of males at birth and subsequently in Groups 2 and 3 relative to Group 1 (at birth: Group 3: 58.2%; Group 2: 54.1%; Group 1: 52.1%) these incidences did not appear to be statistically significant.

There were no significant differences between puppies from the 3 groups with respect to physiological parameters (mean body weights, mean rectal temperatures, mean respiratory rates, mean heart rates) measured on post-parturition days 14, 28 and 42.

Although no dogs were dosed at the 5x level, and no blood was taken for clinical chemistry and hematology measurements, the purpose of this study was to allow a label claim for use of at least two registered products (EPA Reg. Nos. 65331-3 and 65331-5) on breeding, pregnant and lactating bitches. TRB has previously reviewed a companion animal (dog) study for this formulation which included a 5x dosage group and measurements of clinical chemistry and hematology parameters.

This study is classified as acceptable. The findings of this study are adequate to support the use of EPA Reg. Nos. 65331-3 and 65331-5 at the specified label use rates (varying according to the weight of the dog) at 28-day intervals on breeding, pregnant and lactating bitches.

14. CITAB concludes that the companion animal (dog and puppy) citations (MRIDs 44942104; 45143901; 45612702; and 45620507) adequately support the proposed dosage rates (0.023 fl. oz. or 0.67 mL for dogs/puppies weighing 5-22 lbs; 0.045 fl. oz. or 1.34 mL for 23-44 lbs; 0.091 or 2.68 mL for 45-88 lbs; 0.136 fl. oz. or 4.02 mL for 89-132 lbs). These citations also support a minimum weight of 5 lbs, and a minimum age of 8 weeks. In addition, the study in MRID 45620507 supports the use of this formulation on breeding, pregnant and lactating bitches.
15. All companion animal (870.7200) study requirements for the registration of 91090-U have been satisfied.

Ciarlo, Timothy

From: Jennifer Yentel <Jennifer@PyxisRC.com>
Sent: Thursday, July 28, 2016 4:51 PM
To: Ciarlo, Timothy
Cc: Davis, Kable; IVB1; Janelle Kay
Subject: RE: 91090-U Neove Spot-On for Dogs
Attachments: 91090-U.20160728.Neove Spot-on #003 for Dogs (v3) (clean copy).pdf; 91090-U.20160728.Neove Spot-on #003 for Dogs (v3) (tracked changes).pdf

Follow Up Flag: Follow up
Flag Status: Completed

Hi Tim, Attached is the revised label for 91090-U revised per your additional comments. Both a clean and a tracked-changes copy are attached. If you need anything else, please let me know.

Regards,
Jennifer

Jennifer Yentel
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Jennifer@PyxisRC.com

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]
Sent: Thursday, July 28, 2016 3:40 PM
To: Jennifer Yentel <Jennifer@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; Janelle Kay <Janelle@PyxisRC.com>
Subject: RE: 91090-U Neove Spot-On for Dogs

Hi Jennifer,

Bo and I have some additional comments. Please review the attached PDF and let me know what you think.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: Jennifer Yentel [<mailto:Jennifer@PyxisRC.com>]

Sent: Thursday, July 28, 2016 1:07 PM

Resubmission #1

To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; Janelle Kay <Janelle@PyxisRC.com>

Subject: RE: 91090-U Neove Spot-On for Dogs

Hi Tim,

Attached please find the revised label for Neove Spot On #003 for Dogs (EPA File Symbol No. 91090-U). I've attached a clean version of the label as well as a tracked changes copy. As with the Spot On #003 for Cats, I slightly modified the additional language that you requested in the Physical or Chemical Hazards Section from "Do not mix or allow coming in contact with oxidizing agents. Hazardous chemical reaction may occur." to "Do not mix or allow to come into contact with oxidizing agents. Hazardous chemical reaction may occur.". The modification is grammatical in nature and is only meant to make the statement a little clearer to the end-user. If you have any questions or if there are any additional issues with this label, please let me know.

Best regards,
Jennifer Yentel

Jennifer Yentel
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Jennifer@PyxisRC.com

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]

Sent: Friday, July 22, 2016 3:21 PM

To: Janelle Kay <Janelle@PyxisRC.com>; Jennifer Yentel <Jennifer@PyxisRC.com>

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>

Subject: RE: 91090-U Neove Spot-On for Dogs

Hi Janelle and Jennifer,

Please see my label comments/edits for 91090-U in the attached PDF. If you have any questions or if anything is unclear, please let me know. I'll be standing by for a revised label. FYI, I'll be working on reviewing the label for 91090-L next week and will get that to you shortly with comments.

Have a great weekend!

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]

Sent: Monday, July 18, 2016 9:08 PM

To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; Jennifer Yentel <Jennifer@PyxisRC.com>

Subject: RE: 91090-U Neove Spot-On for Dogs

Tim,

Thanks for the head's up; we were aware of the time-limited registrations as well as the enhanced reporting. I'm traveling this week, so in order to get a quicker turnaround time on the label, please also send comments to Jennifer Yentel (Jennifer@PyxisRC.com) of our offices.

Thanks!

Janelle

Janelle Kay

Pyxis Regulatory Consulting, Inc.

4110 136th St. Ct. NW

Gig Harbor, WA 98332

(T): 253-853-7369

(F): 253-853-5516

(E): Janelle@PyxisRC.com

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]

Sent: Monday, July 18, 2016 7:32 AM

To: Janelle Kay <Janelle@PyxisRC.com>

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>

Subject: RE: 91090-U Neove Spot-On for Dogs

Hi Janelle,

I've received the chemistry, tox, and child resistant packaging reviews for 91090-U and -L and am about to begin my label reviews. I should have some label edits/comments for you in the coming days. In the meantime, I wanted to make you aware that the Agency is issuing time-limited registrations for new pet spot-on products, with an expiration date of two years from the date of registration. Quarterly enhanced incident reports and sales information will also need to be submitted if and when these products are registered.

Please let me know if you have any questions.

Regards,

Tim Ciarlo

Entomologist

Environmental Protection Agency

OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]
Sent: Thursday, May 26, 2016 12:19 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Subject: RE: 91090-U Neove Spot-On for Dogs

Bo,

No problem. I appreciate you looking into this for me. Please continue processing the registration as is.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 253-853-7369
(F): 253-853-5516
(E): Janelle@PyxisRC.com

From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: Thursday, May 26, 2016 8:44 AM
To: Janelle Kay <Janelle@PyxisRC.com>
Cc: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Subject: RE: 91090-U Neove Spot-On for Dogs

Hi Janelle –

I took your question to the PRIA Manger's meeting today and the group decided that modifying the data matrix such that it would result in the need for efficacy and companion animal safety reviews changes the submission too greatly from what was originally submitted. As a result, they would not support a renegotiation. Do you want us to keep moving forward with the registration process or do you wish to withdraw?

Hope all is well.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]
Sent: Tuesday, May 24, 2016 4:01 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Subject: 91090-U Neove Spot-On for Dogs

Bo,

I hope all is well with you. In October, we submitted an application for registration for a product for Shanghai Newway called Neove Spot-On for Dogs (91090-U). They recently contacted me and are considering revising their label and data matrix (the data cited) for a variety of reasons, but most importantly not cite any data of compensable age. This would like entail an efficacy, safety and label review. If Shanghai Newway decided to move forward with these changes, would the Agency consider this and how much of a PRIA extension would you need?

Regards,

Janelle

Janelle Kay
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INERT CLEARANCE STATUS FORM

Reviewer Name: Stephanie Varner			Request Date: Nov 03, 15
Tel: 703-347-0240	ISB	CUBE: S-4813	MAIL CODE:

A. COMMENTS:

The trade name was removed from the CSF so the ingredient is only identified by its approved generic name. A new CSF is included.

B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: 975885	Date on CSF: Sep 28, 15	Food-Use Pesticide: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
EPA Reg. No/File Symbol: 91090-U	Formulation:	
Product Name: Neove Spot On #003 for Dogs		

C. INGREDIENT INFORMATION:

Ingredient No.1	Tolerance Exemption(s) ¹					
	910	920	930	940	950	960
Chem. Name:						
Trade Name: [REDACTED]						
CAS Reg. No.:						
Comments: [REDACTED] is not listed in the Agency database. Please provide a manufacture letter (with letterhead) providing full compositional information including the manufacturer, constituent names, CAS numbers, and weight/weight percentage composition (100% composition).						

Reviewer Name: Stephanie Varner

Review Date: 11/3/15

Varner, Stephanie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Tuesday, November 03, 2015 2:35 PM
To: Varner, Stephanie
Subject: RE: Submission to EPA: Neove Spot On #003 for Dogs (EPA Reg. No. 91090-U)
Attachments: 20150928 Neove Spot On #003 CSF_R1.pdf

Stephanie,

The revised CSF is attached.

Ann

From: Varner, Stephanie [mailto:Varner.Stephanie@epa.gov]
Sent: November 03, 2015 2:25 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: Submission to EPA: Neove Spot On #003 for Dogs (EPA Reg. No. 91090-U)

Hi Ann,

The generic chemical name is found, however the listed the trade name is not in our system. You can send a new CSF with the trade name removed or send the compositional letter I described in the Inert Clearance Form.

Thanks,
Stephanie

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Tuesday, November 03, 2015 1:58 PM
To: Varner, Stephanie <Varner.Stephanie@epa.gov>
Subject: RE: Submission to EPA: Neove Spot On #003 for Dogs (EPA Reg. No. 91090-U)

Stephanie,

This inert is [REDACTED] as denoted on the SDS. A copy of the SDS for this inert is found in Volume 1 of the submission (MRID 49729701). I can send you a copy of the SDS if you can't access Volume 1. If you need further information, please let me know.

Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
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Fax (253) 853-5516
Email Ann@PyxisRC.com